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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/601,029
Filing Date: July 26, 2000
Appellant(s): HIMMELSBACH ET AL.

Neil Greenblum
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/17/2007 appealing from the Office action mailed 8/2/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,527,536	MERKLE	6-1996
6,479,073	LUCAST	11-2002
5,547,223	KOKETSU	8-1996
6,074,965	BODENSCHATZ	6-2000
4,722,857	TOMIOKA	2-1988

5,863,977	FISCHER	1-1999
5,489,624	KANTER	2-1996
5,407,717	LUCAST	4-1995
5,059,189	CILENTO	10-1991
3,967,472	WILDEMAN	7-1976
6,555,730	ALBROD	4-2003

(9) Grounds of Rejection

The following grounds of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 37-43, 45-52 and 55-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 5,527,536 to Merkle et al. (hereinafter referred to as Merkle) in view of USP 6,479,073 to Lucast et al. (hereinafter referred to as Lucast '073) in view of USP 5,547,223 to Koketsu et al. (hereinafter referred to as Koketsu).

Regarding claims 37-43, 45-52 and 55-65, Merkle discloses a backing material for medical purposes, and an adhesive composition on one side of the backing material, the adhesive composition being a hot melt composition comprising a styrene block copolymer, the adhesive composition further comprising at least one pharmacologically active substance (see entire

document including the abstract, column 3, lines 4-10, and the paragraph bridging columns 4 and 5).

Merkle discloses that the backing layer may be a polyester film (see Examples), but Merkle is silent with regards to specific polyester film structures. Therefore, it would have been necessary and thus obvious to look to the prior art for conventional backing layer structures. Lucast '073 provides this conventional teaching showing that it is known in the art to use a nonwoven backing layer overstitched by yarns (see entire document including the paragraph bridging columns 2 and 3). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the backing layer from a nonwoven overstitched by yarns, as taught by Lucast '073, motivated by the expectation of successfully practicing the invention of Merkle and because it is within the general skill of a worker in the art to select a known backing layer structure on the basis of its suitability and desired characteristics.

Lucast '073 does not appear to mention how many stitches (per cm) are present on the backing layer, but Koketsu discloses that it is known in the art that the number of stitches is a result effective variable that would alter the strength of the web, with more stitches supplying a stronger web (see entire document including column 7, lines 16-32). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide 5 to 50 longitudinal stitches per cm in order to create a stitch-bonded fabric with a desired strength and rigidity and because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Regarding claims 39-43, 58-59 and 65, considering that the backing material taught by the applied prior art is substantially identical to the claimed backing material (stitch-bonded

polyester nonwoven with 5 to 50 stitches per cm), it appears that the backing material inherently possesses the claimed properties.

The Patent and Trademark Office can require applicants to prove that prior art products do not necessarily or inherently possess characteristics of claimed products where claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes; burden of proof is on applicants where rejection based on inherency under 35 U.S.C. § 102 or on prima facie obviousness under 35 U.S.C. § 103, jointly or alternatively, and Patent and Trademark Office's inability to manufacture products or to obtain and compare prior art products evidences fairness of this rejection, *In re Best, Bolton, and Shaw*, 195 USPQ 431 (CCPA 1977).

Regarding claims 45 and 46, Merkel discloses that 100% of one side of the backing layer may be coated with the adhesive composition while the other side of the backing layer may be uncoated with the adhesive (see Examples).

Regarding claims 47 and 48, Merkel does not appear to mention the weight per unit area of the adhesive on the backing material, but the amount of adhesive is a result effective variable that would affect the degree of adhesion the tape would have to the skin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide between 90 to 500 grams per square meter of adhesive in order to create a medical tape with the optimum amount of adhesion strength fit for its intended use on human skin and because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Regarding claims 49-52, Merkel discloses that the block copolymer may be a triple-block copolymer wherein the block A comprises polystyrene and the block B comprises one or more monomer units such as ethylene and butylenes (abstract).

Regarding claims 51 and 52, Merkel discloses that the total concentration of styrene in the block copolymer may be 10 to 50 weight percent (column 4, lines 40-42).

Regarding claims 55 and 61, Merkel discloses that adhesive composition may comprise from 10 to 80% block copolymers (column 4, lines 21-43).

Regarding claims 56 and 57, Merkel discloses that the adhesive composition may have a softening point of from 80 to 140C (column 4, lines 55-64).

Regarding claims 60 and 61, Merkel discloses that the pharmacologically active substance may be present in therapeutically active amounts (column 3, lines 4-10). The examiner takes Official Notice that 0.01 to 20% by weight includes therapeutically active amounts.

Regarding claim 62, Merkel does not appear to mention the addition of foaming agents, but Lucast '073 discloses that it is known in the art to add foaming agents to an adhesive (column 5, lines 16-23). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a foaming agent to the adhesive, as disclosed by Lucast '073, because some adhesive applications desire foamed adhesive.

Regarding claim 63, Merkel discloses that the adhesive composition may be on one side of the backing material and a release layer may be on the opposite side (see Examples).

Regarding claim 64, Merkel discloses that the backing material may further comprise a polyester film (considered to read on the claimed wound pad) on the adhesive composition (see Examples).

3. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu as applied to claims 37-43, 45-52 and 55-65 above, and further in view of USPN 6,074,965 to Bodenschatz et al. (hereinafter referred to as Bodenschatz).

Merkel does not appear to mention reinforcing fibers in the backing layer, but Bodenschatz discloses that it is known in the art to use reinforcing fibers having a strength of over 60 cN/tex in a backing layer (see entire document including abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add reinforcing fibers to the backing layer, as taught by Bodenschatz, because the reinforcing fibers would advantageously increase strength.

4. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu as applied to claims 37-43, 45-52 and 55-65 above, and further in view of USPN 4,722,857 to Tomioka et al. (hereinafter referred to as Tomioka).

Merkel does not appear to mention reinforcing fibers in the backing layer, but Tomioka discloses that it is known in the bandage art to use reinforcing fibers in a nonwoven material (see entire document including column 1, lines 6-10, column 3, lines 41-58, and column 8, lines 20-24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add reinforcing fibers to the nonwoven backing layer, as taught by Tomioka,

because the reinforcing fibers would advantageously increase strength. It is noted that Tomioka discloses the use of materials (such as polyester and nylon) substantially identical to the high-strength materials disclosed in the current specification (see page 14, lines 6-11), therefore, it appears the fibers would inherently possess the claimed strength.

5. Claims 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu as applied to claims 37-43, 45-52 and 55-65 above, and further in view of USPN 5,863,977 to Fischer et al. (hereinafter referred to as Fischer).

Regarding claims 53 and 54, Merkle does not appear to mention the addition of a diblock copolymer, but Fischer discloses that it is known in the art to add a diblock copolymer to a triblock copolymer adhesive to improve tack properties and/or improve processability (see entire document including the paragraph bridging columns 2 and 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a diblock copolymer to the triblock copolymer adhesive, as taught by Fischer, to improve tack properties and/or improve processability.

Regarding claim 54, Merkel discloses that the triblock copolymer may be present in an amount of 10 to 80% and a tackifier may be present in an amount of 20 to 90% (column 4, lines 21-52), therefore, the art teaches that the diblock is to be present in an amount of less than 80% by weight.

6. Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu as applied to claims 37-43, 45-52 and 55-65 above, and further in view of USPN 5,489,624 to Kantner et al. (hereinafter referred to as Kantner).

Merkle does not appear to mention incorporating pharmacologically active agents not in co-mixture with the adhesive, but Kantner discloses that adhesive materials in the medical field can frequently be used to transport drugs through the skin (see entire document including abstract). Kantner discloses several examples of biologically active material that would exist in particle form that can be incorporated into the adhesive (see entire document including column 9, lines 28-41 and column 12, lines 14-19). It would have been obvious to a person having ordinary skill in the art at the time of the invention to incorporate active agents not in co-mixture with the adhesive composition in the medical tape, as disclosed by Kantner, in order to provide various healing properties to the tape.

7. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu as applied to claims 37-43, 45-52 and 55-65 above, and further in view of USPN 5,407,717 to Lucast et al. (hereinafter referred to as Lucast '717).

Merkel does not appear to mention sterilizing the adhesive composition, but Lucast '717 discloses that adhesive tapes that are used on human skin must be sterilized (see entire document including column 11, lines 5-10). It would have been obvious to a person having ordinary skill in the art at the time of the invention to sterilize the adhesive composition, as taught by Lucast '717, in order to make it safe for use on human skin.

8. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu as applied to claims 37-43, 45-52 and 55-65 above, and further in view of USPN 5,059,189 to Cilento et al. (hereinafter referred to as Cilento).

Merkle appears to be is silent with regards to specific pharmacologically active substances, therefore, it would have been necessary and thus obvious to look to the prior art for conventional pharmacologically active substances. Cilento provides this conventional teaching showing that it is known in the art to use pharmacologically active substances such as camphor, lidocaine, or the like (see entire document including column 6, lines 24-41). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the pharmacologically active substance from camphor or lidocaine, as disclosed by Cilento, motivated by the expectation of successfully practicing the invention of Merkle.

9. Claims 69-73, 75-82 and 85-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu in view of USPN 3,967,472 to Wildeman et al. (hereinafter referred to as Wildeman).

Regarding claims 69-73, 75-82 and 85-95, Merkle discloses a backing material for medical purposes, and an adhesive composition on one side of the backing material, the adhesive composition being a hot melt composition comprising a styrene block copolymer, the adhesive composition further comprising at least one pharmacologically active substance (see entire document including the abstract, column 3, lines 4-10, and the paragraph bridging columns 4 and 5).

Merkle discloses that the backing layer may be a polyester film (see Examples), but Merkle is silent with regards to specific polyester film structures. Therefore, it would have been necessary and thus obvious to look to the prior art for conventional backing layer structures. Lucast '073 provides this conventional teaching showing that it is known in the art to use a nonwoven backing layer overstitched by yarns (see entire document including the paragraph bridging columns 2 and 3). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the backing layer from a nonwoven overstitched by yarns, as taught by Lucast '073, motivated by the expectation of successfully practicing the invention of Merkle and because it is within the general skill of a worker in the art to select a known backing layer structure on the basis of its suitability and desired characteristics.

Lucast '073 does not appear to mention how many stitches (per cm) are present on the backing layer, but Koketsu discloses that it is known in the art that the number of stitches is a result effective variable that would alter the strength of the web, with more stitches supplying a stronger web (see entire document including column 7, lines 16-32). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide 5 to 50 longitudinal stitches per cm in order to create a stitch-bonded fabric with a desired strength and rigidity and because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Lucast '073 does not appear to mention the stitches of the fabric being formed from loops from the fibers of the web, but Wildeman discloses that it is known in the art that stitch-bonded fabrics may be stitched with the loops from the web (see entire document including column 3, lines 40-68). It would have been obvious to a person having ordinary skill in the art at the time

of the invention to stitch the fabric of Lucast '073 with loops from the web, as disclosed by Wildeman, in order to avoid using extra stitching thread.

Regarding claims 71-73, 88-89 and 95, considering that the backing material taught by the applied prior art is substantially identical to the claimed backing material (stitch-bonded polyester nonwoven with 5 to 50 stitches per cm), it appears that the backing material inherently possesses the claimed properties.

Regarding claim 72, Merkel does not appear to mention the use of a polyamide (such as nylon) for the backing material, but Lucast '073 discloses that it is known in the art to use nylon backing material (column 3, lines 19-36). Considering that the specification teaches that a backing material of this kind generates the claimed property (see page 10, lines 1-8), it appears that the backing material inherently possesses the claimed property.

Regarding claims 75 and 76, Merkel discloses that 100% of one side of the backing layer may be coated with the adhesive composition while the other side of the backing layer may be uncoated with the adhesive (see Examples).

Regarding claims 77 and 78, Merkel does not appear to mention the weight per unit area of the adhesive on the backing material, but the amount of adhesive is a result effective variable that would affect the degree of adhesion the tape would have to the skin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide between 90 to 500 grams per square meter of adhesive in order to create a medical tape with the optimum amount of adhesion strength fit for its intended use on human skin and because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Regarding claims 79-82, Merkel discloses that the block copolymer may be a triple-block copolymer wherein the block A comprises polystyrene and the block B comprises one or more monomer units such as ethylene and butylenes (abstract).

Regarding claims 81 and 82, Merkel discloses that the total concentration of styrene in the block copolymer may be 10 to 50 weight percent (column 4, lines 40-42).

Regarding claims 85 and 91, Merkel discloses that adhesive composition may comprise from 10 to 80% block copolymers (column 4, lines 21-43).

Regarding claims 86 and 87, Merkel discloses that the adhesive composition may have a softening point of from 80 to 140C (column 4, lines 55-64).

Regarding claims 90 and 91, Merkel discloses that the pharmacologically active substance may be present in therapeutically active amounts (column 3, lines 4-10). The examiner takes Official Notice that 0.01 to 20% by weight includes therapeutically active amounts.

Regarding claim 92, Merkel does not appear to mention the addition of foaming agents, but Lucast '073 discloses that it is known in the art to add foaming agents to an adhesive (column 5, lines 16-23). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a foaming agent to the adhesive, as disclosed by Lucast '073, because some adhesive applications desire foamed adhesive.

Regarding claim 93, Merkel discloses that the adhesive composition may be on one side of the backing material and a release layer may be on the opposite side (see Examples).

Regarding claim 94, Merkel discloses that the backing material may further comprise a polyester film (considered to read on the claimed wound pad) on the adhesive composition (see Examples).

10. Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu in view of USPN 3,967,472 to Wildeman as applied to claims 69-73, 75-82 and 85-95 above, and further in view of USPN 6,074,965 to Bodenschatz.

Merkel does not appear to mention reinforcing fibers in the backing layer, but Bodenschatz discloses that it is known in the art to use reinforcing fibers having a strength of over 60 cN/tex in a backing layer (see entire document including abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add reinforcing fibers to the backing layer, as taught by Bodenschatz, because the reinforcing fibers would advantageously increase strength.

11. Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu in view of USPN 3,967,472 to Wildeman as applied to claims 69-73, 75-82 and 85-95 above, and further in view of USPN 4,722,857 to Tomioka.

Merkel does not appear to mention reinforcing fibers in the backing layer, but Tomioka discloses that it is known in the bandage art to use reinforcing fibers in a nonwoven material (see entire document including column 1, lines 6-10, column 3, lines 41-58, and column 8, lines 20-24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add reinforcing fibers to the nonwoven backing layer, as taught by Tomioka,

because the reinforcing fibers would advantageously increase strength. It is noted that Tomioka discloses the use of materials (such as polyester and nylon) substantially identical to the high-strength materials disclosed in the current specification (see page 14, lines 6-11), therefore, it appears the fibers would inherently possess the claimed strength.

12. Claims 83 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu in view of USPN 3,967,472 to Wildeman as applied to claims 69-73, 75-82 and 85-95 above, and further in view of USPN 5,863,977 to Fischer.

Regarding claims 83 and 84, Merkle does not appear to mention the addition of a diblock copolymer, but Fischer discloses that it is known in the art to add a diblock copolymer to a triblock copolymer adhesive to improve tack properties and/or improve processability (see entire document including the paragraph bridging columns 2 and 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a diblock copolymer to the triblock copolymer adhesive, as taught by Fischer, to improve tack properties and/or improve processability.

Regarding claim 84, Merkel discloses that the triblock copolymer may be present in an amount of 10 to 80% and a tackifier may be present in an amount of 20 to 90% (column 4, lines 21-52), therefore, the art teaches that the diblock is to be present in an amount of less than 80% by weight.

13. Claim 96 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu in view of USPN 3,967,472 to Wildeman as applied to claims 69-73, 75-82 and 85-95 above, and further in view of USPN 5,489,624 to Kantner.

Merkle does not appear to mention incorporating pharmacologically active agents not in co-mixture with the adhesive, but Kantner discloses that adhesive materials in the medical field can frequently be used to transport drugs through the skin (see entire document including abstract). Kantner discloses several examples of biologically active material that would exist in particle form that can be incorporated into the adhesive (see entire document including column 9, lines 28-41 and column 12, lines 14-19). It would have been obvious to a person having ordinary skill in the art at the time of the invention to incorporate active agents not in co-mixture with the adhesive composition in the medical tape, as disclosed by Kantner, in order to provide various healing properties to the tape.

14. Claim 97 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu in view of USPN 3,967,472 to Wildeman as applied to claims 69-73, 75-82 and 85-95 above, and further in view of USPN 5,407,717 to Lucast.

Merkel does not appear to mention sterilizing the adhesive composition, but Lucast '717 discloses that adhesive tapes that are used on human skin must be sterilized (see entire document including column 11, lines 5-10). It would have been obvious to a person having ordinary skill in the art at the time of the invention to sterilize the adhesive composition, as taught by Lucast '717, in order to make it safe for use on human skin.

15. Claim 98 is rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu in view of USPN 3,967,472 to Wildeman as applied to claims 69-73, 75-82 and 85-95 above, and further in view of USPN 5,059,189 to Cilento.

Merkle appears to be is silent with regards to specific pharmacologically active substances, therefore, it would have been necessary and thus obvious to look to the prior art for conventional pharmacologically active substances. Cilento provides this conventional teaching showing that it is known in the art to use pharmacologically active substances such as camphor, lidocaine, or the like (see entire document including column 6, lines 24-41). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the pharmacologically active substance from camphor or lidocaine, as disclosed by Cilento, motivated by the expectation of successfully practicing the invention of Merkle.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 37-52, 55-65, 69-82 and 85-95 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of USPN 6,555,730 to Albrod et al. (hereinafter referred to as Albrod) in view of USPN 5,527,536 to Merkle.

Regarding claims 37-52, 55-65, 69-82 and 85-95, Albrod claims a backing material for medical purposes that is similar to the current application. Albrod does not claim a pharmacologically active substance present in the adhesive, but Merkle discloses that it is known in the medical patch art to include a pharmacologically active substance in an adhesive (see entire document including column 3, lines 4-10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a pharmacologically active substance in the adhesive, as taught by Merkle, in order to provide the tape with an enhanced medical function.

Regarding claims 38 and 70, see claim 3 of Albrod.

Regarding claims 39-41 and 71, see claim 1 of Albrod.

Regarding claims 42 and 73, see claim 10 of Albrod.

Regarding claim 43, see claim 7 of Albrod.

Regarding claims 44 and 74, see claim 11 of Albrod.

Regarding claims 45-46 and 75-76, see claim 1 of Albrod.

Regarding claims 47-48 and 77-78, see claim 20 of Albrod.

Regarding claims 49-52 and 79-82, see claim 16 of Albrod.

Regarding claims 55 and 85, see claim 17 of Albrod.

Regarding claims 56-57 and 86-87, Albrod does not claim specific softening temperatures, but Merkel discloses that the adhesive composition may have a softening point of from 80 to 140C (column 4, lines 55-64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the softening temperature from 80 to 140C motivated by the expectation of successfully practicing the invention of Albrod.

Regarding claims 58-59 and 88-89, see claim 13 of Albrod.

Regarding claims 60-61 and 90-91, Merkel discloses that the pharmacologically active substance may be present in therapeutically active amounts (column 3, lines 4-10).

Regarding claims 62 and 92, see claim 21 of Albrod.

Regarding claims 63 and 93, see claim 23 of Albrod.

Regarding claims 64 and 94, see claim 25 of Albrod.

Regarding claims 65 and 95, see claim 9 of Albrod.

Regarding claims 69-82 and 85-95, see claim 2 of Albrod.

Regarding claim 72, see claim 5 of Albrod.

18. Claims 53-54 and 83-84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of USPN 6,555,730 to Albrod in view of USPN 5,527,536 to Merkle as applied to claims 37-52, 55-65, 69-82 and 85-95 above, and further in view of USPN 5,863,977 to Fischer.

Regarding claims 53-54 and 83-84, Merkle does not appear to mention the addition of a diblock copolymer, but Fischer discloses that it is known in the art to add a diblock copolymer to a triblock copolymer adhesive to improve tack properties and/or improve processability (see

entire document including the paragraph bridging columns 2 and 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a diblock copolymer to the triblock copolymer adhesive, as taught by Fischer, to improve tack properties and/or improve processability.

Regarding claims 54 and 84, Merkel discloses that the triblock copolymer may be present in an amount of 10 to 80% and a tackifier may be present in an amount of 20 to 90% (column 4, lines 21-52), therefore, the art teaches that the diblock is to be present in an amount of less than 80% by weight.

19. Claims 66 and 96 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of USPN 6,555,730 to Albrod in view of USPN 5,527,536 to Merkle as applied to claims 37-52, 55-65, 69-82 and 85-95 above, and further in view of USPN 5,489,624 to Kantner.

Merkle does not appear to mention incorporating pharmacologically active agents not in co-mixture with the adhesive, but Kantner discloses that adhesive materials in the medical field can frequently be used to transport drugs through the skin (see entire document including abstract). Kantner discloses several examples of biologically active material that would exist in particle form that can be incorporated into the adhesive (see entire document including column 9, lines 28-41 and column 12, lines 14-19). It would have been obvious to a person having ordinary skill in the art at the time of the invention to incorporate active agents not in co-mixture with the adhesive composition in the medical tape, as disclosed by Kantner, in order to provide various healing properties to the tape.

20. Claims 67 and 97 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of USPN 6,555,730 to Albrod in view of USPN 5,527,536 to Merkle as applied to claims 37-52, 55-65, 69-82 and 85-95 above, and further in view of USPN 5,407,717 to Lucast.

Merkle does not appear to mention sterilizing the adhesive composition, but Lucast '717 discloses that adhesive tapes that are used on human skin must be sterilized (see entire document including column 11, lines 5-10). It would have been obvious to a person having ordinary skill in the art at the time of the invention to sterilize the adhesive composition, as taught by Lucast '717, in order to make it safe for use on human skin.

21. Claims 68 and 98 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of USPN 6,555,730 to Albrod in view of USPN 5,527,536 to Merkle as applied to claims 37-52, 55-65, 69-82 and 85-95 above, and further in view of USPN 5,059,189 to Cilento.

Merkle appears to be silent with regards to specific pharmacologically active substances, therefore, it would have been necessary and thus obvious to look to the prior art for conventional pharmacologically active substances. Cilento provides this conventional teaching showing that it is known in the art to use pharmacologically active substances such as camphor, lidocaine, or the like (see entire document including column 6, lines 24-41). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the pharmacologically active substance from camphor or lidocaine, as disclosed by Cilento, motivated by the expectation of successfully practicing the invention of Merkle.

(10) Response to Argument

Claims 37-43, 45-52 and 55-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu

1-3. The applicant asserts that there is no motivation to look for other backing layer structures and/or replace the backing layer structure. The examiner respectfully disagrees.

Lucast '073 discloses that it is known in the art that a nonwoven, overstitched by yarns, is a viable backing layer alternative to a polymeric film (see paragraph bridging columns 2 and 3). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a nonwoven, overstitched by yarns, as the backing layer material, because it is a viable backing layer alternative to a polymeric film and because it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability and desired characteristics. It is noted that the appellant has failed to show, or attempt to show, that the substitution yields more than a predictable result.

The substitution of known equivalent structures involves only ordinary skill in the art. *In re Fout* 213 USPQ 532 (CCPA 1982); *In re Susi* 169 USPQ 423 (CCPA 1971); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *In re Ruff* 118 USPQ 343 (CCPA 1958). When a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result. **KSR v. Teleflex**

4-5. The appellant asserts that one skilled in the art would be discouraged to use a nonwoven as a backing layer. The examiner respectfully disagrees.

The appellant asserts that one skilled in the art would be "discouraged" to use a nonwoven instead of a film because there would be a "substantially higher risk" that the adhesive would "evaporate through and/or ooze out of the backing material." The examiner respectfully disagrees. Firstly, the applicant has failed to show, or attempt to show, that the adhesive would necessarily evaporate through and/or flow through the nonwoven material. It is well established that unsupported arguments are no substitute for objective evidence. Secondly, Merkle discloses that "Preferably, the...adhesive composition is applied onto the removable protective layer...and covered with the backing layer." (see the paragraph bridging columns 4 and 5) Clearly the adhesive would not flow through the nonwoven backing layer because it is adhered to the protective layer. Thirdly, the applicant has failed to show, or attempt to show, how the alleged partial "oozing" would destroy the invention of Merkle.

6. The appellant asserts that there is no motivation to combine Merkle and Lucast '073 with Koketsu. The examiner respectfully disagrees.

Lucast '073 does not appear to mention how many stitches (per cm) are present on the backing layer, but Koketsu discloses that it is known in the art that the number of stitches is a result effective variable that would alter the strength of the web, with more stitches supplying a stronger web (see entire document including column 7, lines 16-32). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide at least 3 stitches per cm, such as 5 to 50 stitches per cm, in order to create a stitch-bonded fabric with a

desired strength and rigidity and because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

In response to applicant's argument that Koketsu is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Koketsu is at least reasonably pertinent to the particular problem with which the applicant was concerned which is the proper number of stitches to obtain a desired fabric strength (see page 9, lines 9-18 of the current specification and column 7, lines 16-32 of Koketsu).

7. The appellant asserts that Koketsu fails to teach or suggest that the sewing strength could be improved by increasing the number of stitches per unit length. The examiner respectfully disagrees.

Even though Koketsu may be referring to increasing the overall number of stitches, while keeping the number of stitches per unit length the same, Koketsu clearly teaches that additional stitches increases sewing strength. A person of ordinary skill is also a person of ordinary creativity, not an automaton. It would have been obvious to one having ordinary skill in the art at the time the invention was made to increase the number of stitches per unit length, motivated by a desire to increase the sewing strength. It would have been obvious to one having ordinary skill in the art at the time the invention was made to increase the number of stitches per unit length, as opposed to increasing the number of stitches by increasing the stitch row length, based on design choice and/or because some applications do not allow for additional stitch row length.

Claims 69-73, 75-82 and 85-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,527,536 to Merkle in view of USPN 6,479,073 to Lucast in view of USPN 5,547,223 to Koketsu in view of USPN 3,967,472 to Wildeman.

The appellant asserts that no motivation exists to combine Wildeman with the applied prior art. The examiner respectfully disagrees.

Lucast '073 does not appear to mention the stitches of the fabric being formed from loops from the fibers of the web, but Wildeman discloses that it is known in the art that stitch-bonded fabrics may be stitched with the loops from the web (see entire document including column 2, lines 7-33 and column 3, lines 40-68). It would have been obvious to a person having ordinary skill in the art at the time of the invention to stitch the fabric of Lucast '073 with loops from the web, as disclosed by Wildeman, in order to avoid using extra stitching thread, increase strength, improve pilling, improve abrasion resistance, and/or a much wider range of patterning and surface texture possibilities.

In response, the appellants assert that "they fail to see why improved pilling and abrasion resistance and a much wider range of patterning and surface texture possibilities would motivate one of ordinary skill in the art to employ the technique disclosed in Wildeman." The examiner contends that the backing material of Merkle may be used as a skin patch (column 1, lines 10-20). One skilled in the art would desire to increase fabric strength at least to increase the lifespan of the skin patch and/or to resist failure. One skilled in the art would desire to at least improve pilling to increase the lifespan of the skin patch and/or to improve aesthetic appearance of the skin patch. One skilled in the art would desire to improve abrasion resistance to at least increase the lifespan of the patch. One skilled in the art would desire to improve the range of patterning

and surface texture possibilities because the patch is attached to the skin and different parts of the body possess different patterns and textures. In addition, one skilled in the art would desire to use less stitching thread at least to decrease costs.

In response to applicant's argument that Wildeman is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Wildeman is at least pertinent to the particular problem with which the applicant was concerned, which is increasing the strength of a stitch bonded fabric (see page 1, lines 21-26 of the current specification). In addition, Wildeman is in the field of applicant's endeavor, which is stitch bonded fabrics with stitches formed by loops.

Regarding claims 39-41 and 71, the appellant asserts that the applied prior art fails to teach or suggest the claimed ultimate tensile strength. The examiner respectfully disagrees.

Considering that the backing material taught by the applied prior art is substantially identical to the claimed backing material (stitch-bonded polyester nonwoven with at least 3 stitches per cm and stitches formed by loops from fibers of the nonwoven), it appears that the backing material inherently possesses the claimed property. It is noted that the appellant has failed to show, or attempt to show, that the backing material taught by the applied prior art lacks the claimed property.

Regarding claims 42 and 73, the appellant asserts that the applied prior art fails to teach or suggest the claimed water retention capacity. The examiner respectfully disagrees.

Considering that the backing material taught by the applied prior art is substantially identical to the claimed backing material (stitch-bonded polyester nonwoven with at least 3 stitches per cm and stitches formed by loops from fibers of the nonwoven), it appears that the backing material inherently possesses the claimed property. It is noted that the appellant has failed to show, or attempt to show, that the backing material taught by the applied prior art lacks the claimed property.

Regarding claim 43, the appellant asserts that the applied prior art fails to teach or suggest the claimed ultimate tensile stress elongation. The examiner respectfully disagrees.

Considering that the backing material taught by the applied prior art is substantially identical to the claimed backing material (stitch-bonded polyester nonwoven with at least 3 stitches per cm and stitches formed by loops from fibers of the nonwoven), it appears that the backing material inherently possesses the claimed property. It is noted that the appellant has failed to show, or attempt to show, that the backing material taught by the applied prior art lacks the claimed property.

Regarding claims 47, 48, 77 and 78, the appellant asserts that the applied prior art fails to teach or suggest the claimed adhesion composition amount. The examiner respectfully disagrees.

Merkel does not appear to mention the weight per unit area of the adhesive on the backing material, but the amount of adhesive is a result effective variable that would affect the degree of adhesion the tape would have to the skin. It would have been obvious to one having

ordinary skill in the art at the time the invention was made to provide between 90 to 500 grams per square meter of adhesive in order to create a medical tape with the optimum amount of adhesion strength fit for its intended use on human skin and because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Regarding claims 58, 59, 88 and 89, the appellant asserts that the applied prior art fails to teach or suggest the claimed adhesive composition dynamic complex glass transition temperature. The examiner respectfully disagrees.

Considering that the adhesive composition taught by the applied prior art is substantially identical to the claimed adhesive composition (a hot melt composition comprising a styrene block copolymer and at least one pharmacologically active substance), it appears that the adhesive composition inherently possesses the claimed property. It is noted that the appellant has failed to show, or attempt to show, that the backing material taught by the applied prior art lacks the claimed property.

Regarding claims 64 and 94, the appellant asserts that the applied prior art fails to teach or suggest that the backing material may further comprise a wound pad or a padding on the adhesive composition. The examiner respectfully disagrees.

Merkel discloses that the backing material may further comprise a polyester film silicone-coated on both sides (also known as a removable protective layer) on the adhesive composition (see Examples). The polyester film silicone-coated on both sides is considered to read on the claimed wound pad.

In response, the appellant asserts that the film is not intended for use as a pad because it is thin. The examiner respectfully disagrees. The definition of a “pad” is “a thin, cushionlike

mass of soft material used to fill, to give shape, or to protect against jarring, scraping, or other injury.” (The American Heritage Dictionary) Considering that the appellant admits that film is thin, Merkle discloses that the film is a “protective” layer, and that polyester is clearly a soft material, it is clear that the film can be considered a pad.

Regarding claims 65 and 95, the appellant asserts that the applied prior art fails to teach or suggest that the backing material can be torn by hand as claimed. The examiner respectfully disagrees.

Considering that the backing material taught by the applied prior art is substantially identical to the claimed backing material (stitch-bonded polyester nonwoven with at least 3 stitches per cm and stitches formed by loops from fibers of the nonwoven), it appears that the backing material inherently possesses the claimed property. It is noted that the appellant has failed to show, or attempt to show, that the backing material taught by the applied prior art lacks the claimed property.

Regarding claims 68 and 98, the appellant asserts that the applied prior art fails to teach or suggest that the at least one pharmacologically active substance comprises one or more of the claimed substances. The examiner respectfully disagrees.

Merkle does not appear to mention one of the specific substances, but Cilento discloses that it is known in the art to use pharmacologically active substances such as camphor, lidocaine, or the like (see entire document including column 6, lines 24-41). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use camphor or lidocaine, because it is a viable alternative to the disclosed pharmacologically active substances,

and because it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability and desired characteristics. *In re Leshin*, 125 USPQ 416.

The substitution of known equivalent structures involves only ordinary skill in the art. *In re Fout* 213 USPQ 532 (CCPA 1982); *In re Susi* 169 USPQ 423 (CCPA 1971); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *In re Ruff* 118 USPQ 343 (CCPA 1958). When a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result. **KSR v. Teleflex**

Claims 37-98 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over at least USPN 6,555,730 to Albrod in view of USPN 5,527,536 to

Merkle.

The appellant asserts that no motivation exists to combine Albrod with Merkle. The examiner respectfully disagrees.

Albrod does not claim a pharmacologically active substance present in the adhesive, but Merkle discloses that it is known in the medical patch art to include a pharmacologically active substance in an adhesive (see entire document including column 4, lines 21-42). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a pharmacologically active substance in the adhesive, as taught by Merkle, in order to provide the tape with an enhanced medical function.

The appellant asserts that the pharmacologically active substance disclosed by Merkle would be unsuitable for use in combination with the backing material claimed by Albrod. The examiner respectfully disagrees.

The appellant asserts that the pharmacologically active substance disclosed by Merkle would be unsuitable for the nonwoven material because there would be a risk that the active substance would evaporate through and/or ooze out of the backing material. The examiner respectfully disagrees. Firstly, the applicant has failed to show, or attempt to show, that the active substance would necessarily evaporate through and/or flow through the nonwoven material. It is well established that unsupported arguments are no substitute for objective evidence. Secondly, the applicant has failed to show, or attempt to show, how the alleged "oozing" would destroy the invention of Albrod. Thirdly, Merkle discloses that active substance dissolves in the hot melt adhesive (paragraph bridging columns 4 and 5) and that the adhesive can take up a large amount of active substance without loss of cohesiveness or adhesive strength (column 5, lines 9-20). Clearly the active substance would not evaporate through and/or ooze out of the backing because the adhesive retains cohesiveness. Fourthly, Merkle discloses that "Preferably, the...adhesive composition is applied onto the removable protective layer...and covered with the backing layer." (see the paragraph bridging columns 4 and 5) Clearly the active substance adhesive would not flow through the nonwoven backing layer because it is adhered to the protective layer.

Art Unit: 1794

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Andrew T Piziali/

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